

sores), and medication-related risks (liver failure, blood clot). OS was held constant at 32 months. Trade-off questions were based on predetermined experimental design with known statistical properties. Random-parameters logit model was used to estimate a preference weight for each attribute level. Preference weights were used to calculate maximum levels of risks patients were willing to accept for increases in PFS. **RESULTS:** A total of 138 US subjects completed the survey. PFS was the most important attribute to patients over the range of levels included in the survey, while remaining attributes were ranked in order of importance as: fatigue, diarrhea, liver failure, hand-foot syndrome, blood clot, mouth sores. Increasing PFS by 10 months was as important as avoiding severe fatigue and 2-times as important as avoiding severe mouth sores. Patients were willing to accept blood-clot risks up to 5.5% (95% CI: 3.6%–8.6%) and liver-failure risks up to 3.6% (95% CI: 2.6%–4.8%) to increase PFS by 10 months. **CONCLUSIONS:** PFS is a clinical outcome that is important to RCC patients. Patients were willing to accept higher treatment-related risks to increase PFS.

PRO LABELLING CLAIMS IN ANTINEOPLASTIC AGENTS

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OBJECTIVES: To review PRO labelling claims achieved in antineoplastic products in Europe and in the US. **METHODS:** PROLabels database was searched with neoplasm and oncology as keywords to identify antineoplastic agents with PRO labeling claims approved or revised in Europe since 1995 and in the US since 1998. FDA and EMEA websites and guidances were reviewed. Anti-emetic and analgesic products were not included. **RESULTS:** Among the 101 antineoplastic products approved, 18 were identified with PRO claims—10 in the U.S, 8 in Europe (including one in both agencies)—for 11 different indications: non-small cell lung carcinoma, prostatic neoplasms, small cell lung carcinoma, Kaposi sarcoma, chronic myeloid leukemia, astrocytoma, pleural malignant mesothelioma, breast neoplasms, head & neck neoplasms, stomach neoplasms and colorectal neoplasms. Survival was primary endpoint for 12 products. Other primary endpoints included time to progression, response rate and response duration. PROs included in labels were primary endpoints in only two cases: one product used in prostatic neoplasms (improvement in pain) and one product approved for pancreatic neoplasms (clinical benefit response including pain intensity, use of rescue medication and performance status). Both products were approved by the FDA. Health-related quality of life was clearly mentioned in the label of 7 products (4 approved by the EMEA including 2 approved after the publication of the EMEA and FDA guidances, and 3 by the FDA, all approved before the publication of the guidances). Of these 7 products, 3 approved by the EMEA and 1 by the FDA had an indication for non-small cell lung carcinoma. **CONCLUSIONS:** PROs are rarely used as primary endpoints in approval of antineoplastic agents except for assessing palliative response. When assessed, health-related quality of life is used as a supportive endpoint, and more often associated with non-small cell lung carcinoma, especially in Europe.

LITERATURE REVIEW AND PRODUCT LABEL CLAIM REVIEW FOR THE DEVELOPMENT OF A PATIENT-REPORTED OUTCOME RESEARCH STRATEGY FOR CANCER-RELATED ANEMIA

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OBJECTIVES: An appraisal of patient-reported outcome (PRO) endpoints and existing instruments to measure such endpoints was conducted to identify and critically review potentially relevant and appropriate instruments for use in clinical trials of cancer-related anemia (CRA). The purpose of the study was to determine what PRO endpoints and instruments have been used to assess the impact of treatment in reducing CRA symptoms, and whether the instruments identified were likely to be of the standard acceptable by regulatory authorities to support a label claim. **METHODS:** A systematic search and review of 1486 published scientific abstracts was conducted using MEDLINE and EMBASE, as well as the supporting statements in regulatory agency labels for drugs used in the treatment of anemia. Consistency of the identified PRO measures and their psychometric properties with the current Food and Drug Administration (FDA) draft guidance on PROs supporting a labeling claim was also evaluated. **RESULTS:** A total of 29 instruments were identified. Four instruments were found to support a label claim or used specifically in the CRA population (FACT-F, FACT-An, CLAS/LASA, EORTC QLQ-C30); these were assessed further. Twenty-five were excluded from further assessment because they were specific to a particular disease other than cancer and covered aspects specific to these diseases which were not relevant to the CRA population. Other exclusion reasons included measurement of general health or health-related quality of life (HRQOL) and other symptoms that were neither specific to cancer nor anemia. **CONCLUSIONS:** None of the four instruments assessed were found to meet all the criteria in the FDA draft guidance; however, the findings help inform the design of new PRO instruments for CRA.

HEALTH RELATED QUALITY OF LIFE, FEAR OF RECURRENCE, IMPACT OF EVENTS, ILLNESS INTRUSIVENESS AND PSYCHOLOGICAL DISTRESS IN NON-MUSCLE INVASIVE BLADDER CANCER PATIENTS

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OBJECTIVES: The purpose of this study was to explore differences among Veterans and private-patients on health related quality of life (HRQOL), fear of recurrence (FOR), impact of events (IE), illness intrusiveness (IITF) and psychological distress in non-muscle invasive bladder cancer (NMIBC) patients and provide direction for further study. **METHODS:** Cross sectional study design was used. Participants were drawn from a large private hospital (N = 38) and Veterans Affairs hospital (N = 29) in the southeast United States. HRQOL was measured with EORTC-QLQ-C30. FOR was measured with 5-item measure used in the Cancer of the Prostate Strategic Research Endeavor study. The IE Scale measures subjective response to stress and consists of two subscales, intrusive thoughts and avoidance. The IITF measure assesses impact of illness on functioning and consists of three subscales, intimacy, instrumental life and relationship-personal development. Psychological distress was measured with the Brief Symptom Index (BSI), an 18-item measure. Differences among Veterans vs. private-patients were assessed with student t-test or chi-square as appropriate. Analyses were performed using the SAS v9.1.3. **RESULTS:** Majority of respondents were older (mean age at diagnosis 65.4(± 8.8) years), white (91.1%), males (83.6%), married (70.2%) and largest percentage (35.8%) reported getting some college education. Veterans group did not differ from private-patients on age, education, ethnicity, relationship status, number of bladder cancer treatments received or time since diagnosis (years) (p > 0.05), but differed significantly on gender (p = 0.0016). Number of comorbidities were also higher in the Veterans group (p = 0.0214). Veterans indicated significantly higher FOR, psychological distress, illness intrusiveness on intimacy and instrumental life, and lower HRQOL compared to private-patients (p < 0.05). **CONCLUSIONS:** Veterans had higher level of FOR and psychological distress but lower HRQOL, than private-patients. Interventions to manage patients' fear of recurrence, psychological distress and help them adapt to altered routine may assist NMIBC patients.

EXPLORING THE BURDEN OF ILLNESS ON NEWLY DIAGNOSED ESOPHAGEAL CANCER PATIENTS IN TAIWAN –PRELIMINARY ANALYSIS

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OBJECTIVES: Esophageal cancer (EC) is the seventh cancer among male patients in Taiwan. Difficulty swallowing makes EC patients vulnerable to nutritional challenges and impacts their treatment outcomes and well-being. The aims of this study are to explore the EC patients' burden of illness on nutritional and well-being aspects. **METHODS:** A longitudinal observation study is conducting to recruit newly diagnosed EC patients from the CMU Hospital in Taichung, Taiwan since June 2009. Fresh EC patients were assessed before (T0) and after receiving any main treatments (T1 [1-month], T2 [3-month], T3 [6-month] after treatment(s)) if it is not impossible. Well trained interviewers solicited patients' responses on 1) Nutritional Risk Screen (NRS-2002); 2) Chinese versions of EQ-5D and FACT-E. The descriptive analyses were performed to examine the trends among different stages of EC patients. **RESULTS:** Up to the date of analysis (December 31, 2009), of 27 recruited EC patients, average age was 53 ± 9 years-old and more than 90% were diagnosed with squamous cell carcinoma (85% with clinical stage at III and above). There were 23, 14, 5 and 2 patients completed the T0, T1, T2 and T3 assessments, respectively. Approximately 70% and 80% of patients at T0 and T2 had NR-2002S scored greater than 3 (with defined risk of malnutrition). From T0 to T3, upon the solicited, completed responses, patients seemed to be deteriorated on the daily activities and social well-being (i.e., self-care, usual activity of EQ-5D, and physical and social well-being of FACT-E) but improve on esophageal cancer related symptoms and signs (additional concerns of EC) after treatments. **CONCLUSIONS:** This preliminary analysis showed the extent of EC patients' burden of illness and its change over time. Further assessments are necessary to facilitate the decision making about appropriate management of EC patients on the aspect of nutrition and health-related quality of life.

HEAD-TO-HEAD COMPARISONS OF QUALITY OF LIFE INSTRUMENTS FOR YOUNG ADULT SURVIVORS OF CHILDHOOD AND ADOLESCENT CANCER

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OBJECTIVES: Although several health-related quality of life (HRQOL) instruments exist for adult cancer survivors, little attention has been paid to identify appropriate instruments for young adult survivors of childhood and adolescent cancer (YASCAC). We aim to make head-to-head comparisons of 3 HRQOL instruments for YASCAC. **METHODS:** We collected data via telephone interviews between 05/01/2009 and 09/30/2009 from 141 YASCAC who were off therapy at least 2 years without cancer and enrolled in the CSP and/or the UF Tumor Registry. Each subject reported his/her late effects (yes/no) and HRQOL. HRQOL was measured using the Quality of Life

in Adult Cancer Survivor (QLACS), Quality of Life-Cancer Survivor (QOL-CS), and SF-36. We used Cronbach's alpha coefficient to estimate reliability. We estimated Pearson's correlation coefficients to examine convergent/discriminant validity. We hypothesized homogenous domains (e.g., physical functioning and pain) among 3 instruments would be strongly correlated with each other compared to heterogeneous domains (e.g., physical vs. psychological functioning). We used effect sizes to evaluate late effect known-groups validity which is the extent to which HRQOL scores differ by late effects (yes/no). **RESULTS:** Cronbach's alpha coefficients were acceptable (>0.7) for all domains. Physical domains of the QLACS (e.g., pain) were strongly correlated with the SF-36's physical component summary (PCS), but weakly with mental component summary (MCS). Mental domains of the QLACS (e.g., negative feelings) were strongly correlated with MCS, but weakly with PCS. However, both physical and mental domains of the QOL-CS were strongly correlated with MCS compared to with PCS, suggesting poor convergent/discriminant validity. Effect sizes suggest greater discrimination (>0.5) by the QOL-CS and SF-36 for late effect known-groups compared to the QLACS. **CONCLUSIONS:** The 3 HRQOL instruments are not superior to each other. We suggest using item response theory to select high quality items from different instruments to measure HRQOL for YASCAC more meaningfully.

PCN116

PILOT STUDY FOR EVALUATION OF OUTCOMES OF BREAST CANCER WITH SPECIAL FOCUS ON ECONOMIC IMPACT AND QUALITY OF LIFE
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OBJECTIVES: A pilot study was conducted to evaluate the outcomes of breast cancer and its treatment focusing on economic impact and quality of life in a hospital setting. **METHODS:** Patient interviews were held to measure the economic outcome and standardized tool EORTC QLQ C 30 and its breast specific module QLQ BR 23 was utilized to measure the quality of life. Twenty-seven subjects diagnosed at different stages of the disease were studied. **RESULTS:** The respondent's age ranged between 33–65 yrs with mean age 49.65 (SD = 9.011). The educational status was classified in to four groups, illiterate to university viz; illiterate (25.92%), primary education (22.22%) secondary education (48.14%), and college studies (3.70%). The marital status of the respondents was classified as married and widowed, 81.48% and 18.51% respectively. The distribution of respondents according to TNM staging of breast cancer was observed as first stage (none), stage II (29.62%), stage III (40.74%), and stage IV (14.81%). All patients were treated with a multimodality approach for management. The cost analysis revealed that there are significant differences among different modalities of treatments viz; module one (Rs.1.00 lakh), module two (Rs.1.57 lakh) and module three (Rs.1.09 lakh). The quality of life study revealed that there are differences in the functional scales as well as symptoms scales among the patients treated with different treatment regimens. **CONCLUSIONS:** Breast cancer is a disease, where there is a lot of scope for pharmaceutical care in order to improve the functional scales and global health and to decrease symptoms scales of breast cancer patients. **Key words:** Breast cancer, outcomes, quality of life.

PCN117

QUALITY OF LIFE SCALE FOR PATIENTS WITH HAND-FOOT SYNDROME : FIRST RESULTS

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OBJECTIVES: The aim of this study is to develop and validate a hand-foot syndrome-specific quality of life scale to be able to measure the impact of the condition on patients and to be able to assess the value of certain specific treatments in this indication. **METHODS:** Forty-four patients were included during clinical consultation. **RESULTS:** A total of 61.91% of patients declared having their first episode of HFSR. The mean age was 56.5 years and the population was represented by 75% of female. A total of 2.27%, 29.55%, 38.64% and 29.55% of patients graded 0, 1, 2, 3 in the disease severity; 14.63% of patients have their HFSR located on the hands, 24.39% on feet, 60.98% on both hands and feet. The mean global score of the HFS 14 questionnaire is 37.63 (2–100). The mean score in grade 1 patients is 16.68, 41.18 in grade 2 patients, 53.09 in grade 3 patients. There is a significant difference between these 3 mean scores ($p < 0.0001$). The HFS 14 score is positively and significantly correlated to the DLQI and the Skindex-16 scores. The correlation coefficient between the HFS 14 and the DLQI questionnaires is 0.71324 ($p < 0.0001$). The correlation coefficient between the HFS 14 and the Skindex16 questionnaires is 0.7347 ($p < 0.0001$). The HFS 14 score is negatively correlated with the SF-12 score. The correlation coefficient is significantly different from 0 concerning physical dimension ($p = 0.0027$). The correlation coefficient is not significantly different from 0 concerning the mental dimension. The p-value is 0.4457. The HFS 14 score is positively and significantly correlated to the pain measured by the visual analogue scale ($p < 0.0001$). The correlation is estimated 0.68142. **CONCLUSIONS:** The HFS 14 (or short version) meets requirements of QoL scale and is easy to use. The questionnaire is able to assess the clinical efficacy of new specific treatments developed for HFSR.

USING DISCRETE CHOICE EXPERIMENTS TO ESTIMATE THE MARGINAL WILLINGNESS TO PAY OF INSURANCE PREMIUM FOR STOMACH CANCER TREATMENT IN KOREA

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OBJECTIVES: This study, using DCE method, figures out the characteristics of the decision-making for stomach cancer treatment and investigates the attributes affecting the respondents' choice. Also it ascertains marginal willingness to pay and relative preferences for stomach cancer treatment among the general population of 600 respondents in Korea. **METHODS:** In the survey, the respondents are asked to choose more than one discrete choice option, resulting in multiple observations for each individual. For each pair-wise comparison of choice set, the respondent will make a choice among three alternatives; A, B, or opt out. Thus, the nested-logit model using full maximum likelihood allows us to empirically estimate multi-levels of dependent variables. For the robustness check of our empirical results, we try considering the nature of distribution of error terms in the utility function in several ways. The survey questionnaire includes four attributes associated with stomach cancer in Korea (incidence rates, survival rates in five years after treatment, total treatment costs, and monthly insurance premium), socio-economic status, antecedent variables, along with questions regarding risk averseness and subjective health evaluation. **RESULTS:** The estimates of MWTP between survival rate and monthly insurance premium and MTWP between total treatment costs and monthly insurance premium, by employing "Hybrid Conditional Fixed Effects Logit Model" to figure out the existence of heterogeneity of any observed and unobserved components, are reflecting reasonable range of 176 KRW–194 KRW and 5408 KRW–6945 KRW, respectively. **CONCLUSIONS:** Compared to female counterparts, male respondents have higher MWTP of monthly insurance premium for two related attributes. Besides, currently married respondents, with higher income, and higher educational attainments have more MWTP compared to their respective counterparts. One interesting point is that dependents' MWTP is higher than that of insurance premium payers even after controlling for any other variables.

PCN119

USING DISCRETE CHOICE EXPERIMENTS TO ESTIMATE THE WILLINGNESS TO PAY FOR CANCER TREATMENT IN KOREA: A GENERAL POPULATION STUDY

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OBJECTIVES: This study, using DCE method, figures out the characteristics of the decision-making for cancer treatment and investigates the attributes affecting the respondents' choice. Also it ascertains marginal willingness to pay and relative preferences for cancer treatment among the general population. **METHODS:** In the survey, the respondents are asked to choose more than one discrete choice option, resulting in multiple observations for each individual. For each pair-wise comparison of choice set, the respondent will make a choice among three alternatives; A, B, or opt out. Thus, the nested-logit model using full maximum likelihood allows us to empirically estimate multi-levels of dependent variables. For the robustness check of our empirical results, we try considering the nature of distribution of error terms in the utility function in several ways. The key assumption of logit models is the independence of irrelevant alternatives (IIA), which results from the assumption that other alternatives are independent. The validity of IIA assumption can be simply conducted by a Hausman-McFadden test. We also consider an alternative specification where error terms are independently, but not identically distributed. And finally stand errors are calculated by using bootstrapping and compared to the previous results. **RESULTS:** In this DCE study, evidence of reliability was found at both input and output level. The estimates of MWTP between survival rate and monthly insurance premium and MTWP between total treatment costs and monthly insurance premium, by employing "Hybrid Conditional Fixed Effects Logit Model" to figure out the existence of heterogeneity of any observed and unobserved components, are reflecting reasonable range of 817 KRW–1,324 KRW, and 23,690 KRW–38,139 KRW, respectively. **CONCLUSIONS:** Compared to female counterparts, male respondents have higher MWTP of monthly insurance premium for two related attributes. Besides, currently married respondents, with higher income, and higher educational attainments have more MWTP compared to their respective counterparts.

PCN120

USING DISCRETE CHOICE EXPERIMENTS TO ESTIMATE THE MARGINAL WILLINGNESS TO PAY OF INSURANCE PREMIUM FOR LUNG CANCER TREATMENT IN KOREA

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OBJECTIVES: This study, using DCE method, figures out the characteristics of the decision-making for lung cancer treatment and investigates the attributes affecting the respondents' choice. Also it ascertains marginal willingness to pay and relative preferences for lung cancer treatment among the general population of 600 respondents in Korea. **METHODS:** In the survey, the respondents are asked to choose more than one discrete choice option, resulting in multiple observations for each individual. For each pair-wise comparison of choice set, the respondent will make a choice among three alternatives; A, B, or opt out. Thus, the nested-logit model using full maximum likelihood allows us to empirically estimate multi-levels of dependent variables. For the robustness check of our empirical results, we try considering the nature of distribution